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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,094	06/25/2003	Don J. Diamond	1954-410	7356
6449 7590 06/14/2007 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 1648	PAPER NUMBER
			NOTIFICATION DATE 06/14/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

# Office Action Summary

Application No.

10/603,094

Applicant(s)

DIAMOND, DON J.

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 19 March 2007. Claims 1-14 are pending. Claims 3, 4 and 12-14 are withdrawn. Claims 1, 2 and 5-11 are under non-final rejection.

#### ***Claim Objections***

The objection to claim 5 is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 8 under 35 U.S.C. §112, second paragraph, as being indefinite is withdrawn in response to the Applicants' amendment.

Claim 5 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "said CMV pp65 CTL epitope peptide" in the second line. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1, 2, 5, 6, and 9-11 under 35 U.S.C. §102(e) as being anticipated by Khanna *et al.* (US 2005/0019344 A1) is withdrawn in view of Applicant's argument that the effective filing date is 26 June 2002, which is later than the current filing date of 25 June 2002.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 7 and 8 under 35 U.S.C. §103(a) as being obvious over Khanna *et al.* (US 2005/0019344 A1) in view of Krieg *et al.* (WO122972, 30 April 2001) **is withdrawn** in view of Applicant's argument that the effective filing date is 26 June 2002, which is later than the current filing date of 25 June 2002, and replaced with the following **new rejection**:

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over the Australian patent No. PR5931 (26 June 2001) in view of

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Livingston *et al.* (1999, No. YY in IDS filed on 08 March 2004) and Krieg *et al.* (WO122972, 30 Apr 2001).

The instant claims are drawn to a cytomegalovirus vaccine which comprises a fusion peptide composed of a T helper epitope fused to a CMV CTL epitope peptide. Claims 2 and 11 further limit the T helper epitope to a PADRE. Claims 7 and 8 further limit the vaccine to comprise a DNA adjuvant.

PR5931 describes a vaccine composition (page 2, line 8) comprising a pharmaceutically acceptable carrier and at least one HCMV T-cell epitope (page 7, line 33-36). PR5931 further describes the claimed HCMV pp65 CTL epitope, NLVPMVATV, SEQ ID NO:1 (page 11, line 2).

PR5931 does not describe fusing a CMV CTL epitope to a PADRE epitope or adding a DNA adjuvant.

However, Livingston *et al.* disclose a fusion peptide containing a PADRE epitope fused to a CTL epitope (page 3088, right column, 2<sup>nd</sup> full ¶; page 3089, left column, Material and Methods).

Livingston *et al.* do not disclose a DNA adjuvant.

However, Krieg *et al.* describes immunostimulatory nucleic acids. Specifically, Krieg *et al.* discloses a DNA that matches the sequence of the instantly claimed SEQ ID NO:10. See page 57, SEQ ID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vaccine of PR5931 by fusing the HCMV pp65 CTL epitope to a PADRE as suggested by Livingston *et al.* and by adding a DNA adjuvant as

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taught by Krieg *et al.* The skilled artisan would have been motivated to do so to enhance the amount immune response elicited by the HCMV pp65 CTL epitope. There would have been a reasonable expectation of success, given the disclosure that these DNA adjuvants preferentially activate non-rodent immune cells, as taught by Krieg *et al.* and given that PADRE peptides support the induction and expansion of virus-specific CTL and B cells because the T helper epitopes induce T helper responses that overcome CTL tolerance against specific epitopes, as taught by Livingston *et al.* Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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### **Correspondence**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
07 June 2007



Louise Humphrey, Ph.D.  
Assistant Examiner